IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ADVANCED CARDIOVASCULAR SYSTEMS, INC. and GUIDANT SALES CORPORATION, Plaintiffs, v. MEDTRONIC VASCULAR, INC. and, MEDTRONIC USA, INC. Defendants.	(Civil Action No. 98-80-SLR Now consolidated with Civil Action No. 98-314-SLR and Civil Action No. 98-316-SLR)

ACS'S RESPONSE TO MEDTRONIC'S MOTION FOR NEW TRIAL PURSUANT TO FED. R. CIV. P. 59(a)

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I. INTRODUCTION

Plaintiffs Advanced Cardiovascular Systems, Inc. and Guidant Sales Corporation (collectively "ACS") submit this brief in response to the Motion for New Trial Pursuant to Fed. R. Civ. P. 59(a) filed by Medtronic Vascular, Inc. and Medtronic USA, Inc. (collectively "Medtronic") on April 18, 2005. (D.I. 653.)

II. NATURE AND STAGE OF THE CASE

On February 18, 2005, the jury in this case returned a verdict finding that Medtronic has infringed each of the asserted claims of the Lau patents and that Medtronic failed to prove that any of these claims are invalid. On April 18, 2005, Medtronic filed, *inter alia*, a motion for a new trial. (*Id.*) On June 7-8, 2005, the Court held a bench trial for Medtronic's inequitable conduct defense.

III. SUMMARY OF ARGUMENT

Displeased with the verdict, Medtronic now seeks a new trial and effectively asks the Court to throw out weeks worth of time spent by a jury and the Court to start over from scratch. Medtronic's motion, however, fails to raise any legal or evidentiary errors by the Court—and certainly none that would merit a new trial. Accordingly, the Court should deny Medtronic's motion for a new trial.

Medtronic first argues that the Court erred in its interpretation of the claim terms "undulating pattern," "connected," and "interconnected." As explained in detail in ACS's response to Medtronic's motion for renewed judgment as a matter of law ("JMOL"), however, Medtronic is incorrect. Based on sound principles of claim construction, the Court properly interpreted these terms.

Medtronic also complains that the Court improperly excluded evidence, including testimony relating to the manner in which the Lau inventors allegedly made their invention and

their knowledge of the prior art, alleged misstatements to the U.S. Patent and Trademark Office ("PTO") during prosecution of the Lau patents, and uncorroborated testimony regarding Mr. Boneau's alleged "suture stent" invention. Based on controlling Federal Circuit law, however, such evidence was completely irrelevant to any of the issues in the infringement trial (i.e., validity and infringement of the Lau patents).

Medtronic further contends that the Court should not have granted JMOL on the issue of anticipation based on the Palmaz '417 patent, even though Medtronic's only witness on validity, Professor Saigal, failed to provide testimony from which a reasonable jury could find anticipation. Professor Saigal couched his trial testimony in terms of obviousness, not anticipation, and he relied on multiple references to allege invalidity of any single claim. More specifically, Professor Saigal failed to provide testimony from which a reasonable jury could have concluded that the Palmaz '417 patent discloses an "undulating pattern," "cylindrical elements," or a "longitudinally flexible stent," as recited in the asserted claims. Accordingly, the Court correctly determined that, as a matter of law, Medtronic failed to establish anticipation of the Lau claims based on Palmaz '417.

Medtronic also contends that the Court erred by refusing to apply the law-of-the-case doctrine in the Lau case based on a ruling in the Boneau case. More particularly, Medtronic alleges that the Court's ruling that prosecution history estoppel applied in the Boneau case should somehow bind the parties regarding the validity of the Lau claims. As the Court correctly held, however, the Lau and Boneau cases are different, and the law-of-the-case doctrine does not apply to separate issues in different cases.

Finally, Medtronic raises a frivolous allegation that the Court erred by interpreting the claim term "undulating pattern" after the close of evidence. While Medtronic cites no authority

for this position, the Federal Circuit has held that a trial court has discretion to interpret the claims when the parties have presented a full picture of the claimed invention. That is precisely what the Court did. Accordingly, the Court did not err by issuing its final interpretation of the claims after the close of evidence.

IV. ARGUMENT IN RESPONSE

A. Standard of Review for a New Trial

The "decision to grant or deny a new trial is within the sound discretion of the trial court." *Arthrocare Corp v Smith & Nephew, Inc.*, 310 F. Supp.2d 638, 652 (D. Del. 2004), *vacated in part and remanded on other grounds*, 406 F.3d 1365 (Fed. Cir. 2005). However, "the district court's power to grant a new trial motion is limited to those circumstances where a miscarriage of justice would result if the verdict were to stand." *Olefins Trading, Inc v. Han Yang Chem Corp.*, 9 F.3d 282, 289-90 (3d Cir. 1993) (internal quotations and citations omitted). Applying Third Circuit law, the Federal Circuit will review the Court's decision to grant or deny Medtronic's request for a new trial under the abuse of discretion standard. *Medrad, Inc. v. MRI Devices Corp.*, 401 F.3d 1313, 1322 (Fed. Cir. 2005) ("The Third Circuit applies an abuse of discretion standard in reviewing the denials of motions under Rules 59 and 60.").

Medtronic's motion primarily relates to allegations that the Court improperly excluded evidence and erred in claim construction. Federal Rule of Civil Procedure 61 governs requests for a new trial based on alleged improper exclusion of evidence. Under this rule, "errors in the admission or exclusion of evidence can not be grounds for reversal or a new trial if they constitute harmless error." *Abrams v. Lightolier Inc.*, 50 F.3d 1204, 1213 (3d Cir. 1995). More particularly, the Court will not grant a new trial for improper exclusion of evidence unless (1) the Court finds that it in fact improperly excluded evidence, and (2) the improper exclusion was inconsistent with substantial justice:

> No error in either the admission or the exclusion of evidence and no error or defect in any ruling or order or in anything done or omitted by the court or by any of the parties is ground for granting a new trial or for setting aside a verdict or for vacating, modifying, or otherwise disturbing a judgment or order, unless refusal to take such action appears to the court inconsistent with substantial justice.

Fed. R. Civ. P. 61; *see also Arthrocare*, 310 F. Supp.2d at 666. For evidence excluded under Fed. R. Evid. 403, the Court's ruling "will not be disturbed unless it is 'arbitrary and irrational.'" *Abrams*, 50 F.3d at 1213. Moreover, even if errors had occurred, they would be considered harmless if "it is 'highly probable' that they did not affect a party's substantial rights." *McQueeney v. Wilmington Trust Co.*, 779 F.2d 916, 924 (3d Cir. 1985).

B. The Court Correctly Construed the Terms "Undulating Pattern," "Connected," and "Interconnected"

Medtronic argues that it should be granted a new trial because the Court improperly construed the claim terms "undulating pattern," "connected," and "interconnected." (D.I. 653 at 5-6.) Specifically, Medtronic contends that the term "undulating pattern" requires a combination of U-, W-, and Y-shaped members, and that the terms "connected" and "interconnected" require spacing between adjacent cylindrical elements. (*Id.*)

ACS responds to Medtronic's claim-construction arguments in its response to Medtronic's renewed motion for JMOL, filed concurrently herewith. Rather than repeat these arguments here, ACS refers the Court to its response to Medtronic's renewed motion for JMOL, which is incorporated herein by reference. As explained in detail in ACS's response, the Court correctly construed the terms "undulating pattern," "connected," and "interconnected." Accordingly, the Court should deny Medtronic's request for a new trial on this ground.

C. The Court Correctly Excluded Irrelevant and Unfairly Prejudicial Testimony by the Lau Inventors, Michael Boneau, and Farhad Khosravi

Medtronic complains that the Court excluded testimony by Michael Boneau, Lilip Lau, William Hartigan, and Farhad Khosravi, even though the excluded testimony was irrelevant to patent validity and infringement—the only issues in the infringement trial. While the excluded testimony may have had relevance to Medtronic's failed trade secret action, it was properly excluded under Fed. R. Evid. 402 as irrelevant to the issues in the trial. Moreover, even if the evidence could be considered marginally relevant, the Court properly excluded it under Fed. R. Evid. 403, because the danger of unfair prejudice and jury confusion far outweighed any marginal relevance.

1. The Lau Inventors' Alleged Knowledge of the Boneau Stent Was Legally Irrelevant to Any Issue in the Trial

Medtronic requests a new trial based on the exclusion of irrelevant evidence that the Lau inventors and others at ACS had knowledge of the Boneau stent. (D.I. 653 at 6-7.) Specifically, Medtronic points to proffered testimony by Mr. Boneau regarding alleged meetings with ACS in which Mr. Boneau allegedly disclosed certain stent technology to ACS, and also testimony by Mr. Lau regarding his alleged knowledge of the Boneau stent. (D.I. 653 at 7-16.) Without any legal support, Medtronic argues that such evidence would have been relevant to secondary considerations of non-obviousness and would have prevented ACS from "exaggerat[ing] the novelty of its own stent design."[1] (D.I. 653 at 10-11.) Medtronic also alleges that such evidence would have showed that "ACS had a head start in Dr. Segal's 'horse race'" to develop a second-

[1] Medtronic's validity expert, Professor Saigal, testified that he never considered any secondary considerations of nonobviousness as part of his obviousness analysis. (D.I. 636 at 1427.) Accordingly, even if the Court had excluded relevant evidence related to secondary considerations—which it did not—the exclusion of such evidence would not have affected any of Medtronic's substantial rights. *McQueeney*, 779 F.2d at 924.

generation stent. (D.I. 653 at 9.) Contrary to Medtronic's allegations, however, neither an inventor's knowledge of prior art nor the manner in which he made his invention has any relevance to patentability. *Life Techs., Inc. v. Clontech Labs., Inc.*, 224 F.3d 1320, 1325 (Fed. Cir. 2000) (holding inventor's knowledge of prior art and manner of making invention irrelevant to patentability). Accordingly, the Court correctly excluded this testimony because it had no relevance to any issue in the trial. Moreover, to the extent this proposed testimony had any relevance, the danger of unfair prejudice and jury confusion strongly supports the Court's decision to exclude it under Fed. R. Evid. 403. *Abrams*, 50 F.3d at 1213 (holding court's decision to exclude evidence as unfairly prejudicial under Fed. R. Evid. 403 "will not be disturbed unless it is 'arbitrary and irrational.'").

The Federal Circuit has made clear that evidence of how an invention was made, including an inventor's alleged reliance upon prior art, has no relevance to patentability. In *Life Techs.*, for example, the Federal Circuit held:

> Because patentability is assessed from the perspective of the hypothetical person of ordinary skill in the art, information regarding the subjective motivations of inventors is not material. ... Furthermore, the path that leads an inventor to the invention is expressly made irrelevant to patentability by statute. *See* 35 U.S.C. § 103(a) ("Patentability shall not be negatived by the manner in which the invention was made."). Thus, the inventors' reliance on the Johnson article and the motivations that they derived from it have no bearing on the issue of patentability. It does not matter whether the inventors reached their invention after an exhaustive study of the prior art, or developed their RT enzymes in complete isolation. The only inquiry is whether the teachings of the Johnson article, in combination with other relevant prior art, would have rendered the claimed invention obvious to one of ordinary skill in the art; this inquiry, as a matter of law, is independent of the motivations that led the inventors to the claimed invention.

224 F.3d at 1325 (citations omitted). For the reasons explained in *Life Techs.*, whether or not Mr. Lau and his co-inventors had knowledge of the Boneau stent has no relevance to patent validity.

Moreover, an obviousness analysis does not relate to the skill or knowledge of the actual inventor, and so the skill and knowledge of the Lau inventors is irrelevant. Rather, the relevant inquiry is how a person of ordinary skill in the art would have viewed the prior art:

> The issue of obviousness is determined entirely with reference to a *hypothetical* "person having ordinary skill in the art." It is only that hypothetical person who is presumed to be aware of all the pertinent prior art. The actual inventor's skill is irrelevant to the inquiry, and this is for a very important reason. The statutory emphasis is on a person of *ordinary* skill. Inventors, as a class, according to the concepts underlying the Constitution and the statutes that have created the patent system, possess something—call it what you will—which sets them apart from the workers of *ordinary* skill, and one should not go about determining obviousness under § 103 by inquiring into what *patentees* (i.e., inventors) would have known or would likely have done, faced with the revelations of references.

Standard Oil Co. v. American Cyanamid Co., 774 F.2d 448, 454 (Fed. Cir. 1985) (emphasis added). Accordingly, the Court correctly excluded such testimony as irrelevant.

When deciding this issue during trial, the Court invited Medtronic to cite case law supporting the proposition that an inventor's knowledge of the prior art has relevance to patent validity:

> First of all, it's true that inventors generally take the stand, but it's also true, as accurately set forth in the case cited by ACS, that an inventor's knowledge and an inventor's intent is absolutely irrelevant in terms of the actual legal issues that have to be addressed in infringement and validity.
>
> Now, if you have a case, and although in your—I love sentences like this. There's a legion that flies in the face of virtually every patent case, but I don't think you cited one patent case.

> I don't know a patent case where an inventor's knowledge, his actual knowledge, is relevant to anything but inequitable conduct issues.

(D.I. 633 at 349-50.) Despite the Court's invitation, Medtronic has failed to cite a single case that stands for this erroneous proposition. Indeed, to the contrary, the Federal Circuit law on this point holds that such evidence is completely irrelevant to validity. *Life Techs.*, 224 F.3d at 1325; *Standard Oil*, 774 F.2d at 454. Accordingly, the Court correctly excluded testimony regarding the Lau inventors' alleged knowledge of the Boneau stent and the manner in which they made their invention.

2. ACS Did Not "Open the Door" to Testimony Concerning the Manner in Which Lilip Lau and His Co-Inventors Made Their Invention

While it is beyond dispute that the manner in which an inventor makes an invention is irrelevant to patentability, *Life Techs.*, 224 F.3d at 1325, Medtronic also alleges that ACS somehow "opened the door" to this irrelevant testimony "by telling a 'development' story about how its MultiLink stent purportedly revolutionized balloon angioplasty procedures overnight . . . ."[2] (D.I. 653 at 6.) Medtronic is wrong. Although ACS presented undisputed testimony by interventional cardiologists to explain how the Multilink stent revolutionized treatment of coronary disease, it did not present evidence of the manner in which the Lau inventors went about their inventive process. As the Court correctly held, these are two completely different types of development stories:

> So tell me—plus, it seems to me there's a huge difference in telling the development story in terms of a cardiologist who has discussed what products were available on the market for his use

[2] For William Hartigan, Medtronic proffered irrelevant testimony, allegedly showing that Mr. Hartigan does not remember events that occurred approximately fifteen years ago relating to the manner in which the Lau inventors made their invention. Such evidence was irrelevant, and, therefore, it would have been error to admit it.

> versus what was in the inventor's mind when he was actually going through the inventive process.
>
> Those are two different development stories, and I don't think the one is relevant. Whether people allow each other to put that story on does not make it any more legally relevant.

(D.I. 633 at 350.)

Since ACS did not present any evidence of how the Lau inventors made their invention, it did not "open the door" to otherwise irrelevant testimony on this point. Moreover, Medtronic's proffered evidence certainly did not rebut the undisputed testimony at trial that interventional cardiologists viewed the Lau invention as groundbreaking. Indeed, Medtronic's own interventional cardiologist, Dr. Pearle, agreed that the Multilink stents were "excellent stents" and were improvements over prior-art stents. (D.I. 634 at 747.) That issue simply was not in dispute. Accordingly, the Court correctly held that ACS did not "open the door" to irrelevant testimony as to the manner in which the Lau inventors made their invention. Certainly, the Court's decision to exclude this testimony was not "arbitrary and irrational." *Abrams*, 50 F.3d at 1213.

3. Michael Boneau's Uncorroborated Allegation That He Invented a "Suture Stent" Was Legally Irrelevant to Any Issue in This Case

Medtronic argues that it should have been permitted to introduce uncorroborated testimony of Mr. Boneau, alleging that ACS had knowledge of a prior invention by him relating to a stent formed by suturing together multiple Boneau stents. (D.I. 653 at 9, 11.) Specifically, Medtronic contends, "Mr. Boneau also could have told the jury that he discussed with ACS the idea of connecting single rings (with sutures), again, before Mr. Lau filed his patent application claiming connected rings." (*Id.* at 9.) The Court properly excluded this evidence because Medtronic offered absolutely no corroboration for testimony (1) that Mr. Boneau ever invented a "suture stent," or (2) that he ever communicated such an idea to ACS before the date of the Lau

invention. Notably, Medtronic fails even to acknowledge the Court's basis for excluding this uncorroborated testimony.

As the Court held during trial, evidence of an alleged simultaneous invention requires corroboration by someone other than the purported inventor. (D.I. 586 at 2 ("without corroboration in the form of documents or testimony by someone other than Mr. Boneau, he cannot testify as to the simultaneous invention of 'suture stents.'").) In *Woodland Trust v. Flowertree Nursery, Inc.*, 148 F.3d 1368 (Fed. Cir. 1998), for example, the Federal Circuit explained, "Corroboration of oral evidence of prior invention is the general rule in patent disputes." *Id.* at 1371. Moreover, addressing simultaneous invention in the specific context of obviousness, the court in *Applied Materials, Inc. v. Advanced Semiconductor Materials Am., Inc.*, 1995 WL 261407 (Apr. 25, 1995 N.D. Cal.) similarly ruled:

> Although, as noted, no case has been found expressly discussing corroboration of conception in the context of an obviousness defense, ***the policy behind corroboration for establishing priority applies to a claim that those in the field were familiar with the idea of the invention thus making it obvious***. In other words, if corroboration were not required there would be "a great temptation to perjury" and the absence of such a requirement "would have the effect of virtually precluding the adverse party from the possibility of rebutting such evidence."

Id. at *1 (emphasis added) (attached as Ex. 3). Since Medtronic concedes that it had no corroboration for Mr. Boneau's alleged "suture stent" invention, the Court properly excluded testimony on this issue as legally irrelevant and unfairly prejudicial. (D.I. 586 at 2.)

Furthermore, Medtronic's allegation that Mr. Boneau told ACS about his alleged "suture stent" invention prior to the Lau invention has no basis in the record. In denying Medtronic's trade-secret claim, the Court specifically found, based on undisputed evidence, that the Lau inventors had the idea of connecting together multiple rings by March 1990. (D.I. 543 at 5 ("Around March 5, 1990, [Mr.] Lau, on behalf of ACS, began exploring a stent made up of

multiple sinusoidally patterned rings that were connected together at various points.").) When asked to assume this fact, Mr. Boneau testified that ACS could not have received the idea of connecting multiple stents together from him.

> Q. So if ACS had come up with the idea of connecting stents before the summer of 1990, they could not have received that information from you because you wouldn't—you had no time when you could have communicated it to them, correct?
>
> A. That would be correct.

(Ex. 1, Boneau 4/22/04 Dep. at 298.) Accordingly, Mr. Boneau's uncorroborated testimony would not have established that ACS knew about his alleged "suture stent" invention before the Lau invention date even if that evidence had been admitted. Clearly, the Court's decision to exclude Mr. Boneau's uncorroborated testimony was not "arbitrary and irrational," and therefore does not merit a new trial. *Abrams*, 50 F.3d at 1213.

4. Farhad Khosravi's Deposition Testimony Was Irrelevant

Medtronic complains that the Court improperly excluded deposition testimony of Farhad Khosravi, a former ACS employee, relating to hypothetical questions based on Mr. Khosravi's understanding of an early version of ACS's Multilink stent (i.e., the Bronco) and an early model of a Boneau stent. (D.I. 653 at 12-13.) More particularly, Medtronic proffered the following deposition testimony of Mr. Khosravi:[3]

> Q. Okay. And one last question. Mr. Flores asked you, and there was a quote where you talked about if you made the Boneau out of a tube the same way as the Bronco, would it become the Bronco. And just to be clear for the record, you're not saying if you took the single Boneau stent and you made it out of a tube, it would be the same as a Bronco, correct? You identified a bunch of differences.

[3] Medtronic's proffer left out the last question and answer, in which Mr. Khosravi clearly stated that he did not consider the Boneau stent and ACS's "Bronco" stent prototype at all similar.

A. No, I'm not saying that.

Q. Okay. What are you saying when you say that?

A. I'm saying that if you make the -- make Boneau out of a tube, make the segments short enough, have the number of segments closely enough connected to each other, then effectively it's a Bronco stent.

Q. But do you see the two designs as being at all similar?

A. No.

(Ex. 4, Khosravi 4/30/04 Dep. at 290.) Determining that this testimony related to "inappropriate" subject matter, namely Medtronic's trade secret allegations, the Court excluded it as unfairly prejudicial under Fed. R. Evid. 403. (D.I. 634 at 817.)

While Medtronic contends that Mr. Khosravi's deposition testimony was relevant to Medtronic's obviousness position, this testimony did not concern the Boneau patent itself or any other reference relied upon for obviousness. Indeed, Mr. Khosravi testified that he had never even seen a copy of the Boneau patent application:

Q. Would you review this document, Mr. Khosravi, in sufficient detail to be able to answer the question whether you have ever seen this document before today? Can you answer the question now? Have you ever seen this document before today, our Exhibit 11?

A. No, I have not.

Q. Okay. Did you at any time, while you were at ACS, become aware of the existence of an application for patent on the Boneau stent technology?

A. Not that I can recall.

(Ex. 4, Khosravi 4/30/04 Dep. at 197-98.) Under an obviousness analysis based on the Boneau patent, the proper inquiry related to the disclosure of the Boneau patent, not a model of a Boneau stent. *Torpharm, Inc. v. Ranbaxy Pharm., Inc.*, 336 F.3d 1322, 1327 (Fed. Cir. 2003) ("The test of obviousness vel non is statutory, and requires comparison of the claimed invention to the

relevant prior art."). While Mr. Khosravi's testimony may have had some relevance to Medtronic's failed trade-secret claim, the Court properly excluded it from the patent-infringement trial pursuant to Fed. R. Evid. 403.

D. The Court Correctly Excluded Irrelevant Evidence of Alleged Misstatements to the PTO

Medtronic argues that the Court erred by excluding evidence that "ACS made inaccurate statements to the Patent Office about the characteristics of the Lau invention." (D.I. 653 at 19.) Specifically, Medtronic argues that it should have been permitted to present evidence that ACS mischaracterized the Palmaz '417 patent during prosecution of the Lau '154 patent. Although Medtronic contends that a patentee's statements to the PTO have relevance to validity, Federal Circuit law holds directly to the contrary. Moreover, as explained below, Medtronic's allegations that ACS mischaracterized the Palmaz '417 patent have no merit.

As explained in *Norian Corp. v. Stryker Corp.*, 363 F.3d 1321 (Fed. Cir. 2004), "flawed prosecution arguments do not affect patent validity, whether or not they raise questions of inequitable conduct." *Id.* at 1329. Rather, "[a]fter a patent has issued, validity is determined objectively based on prior art and the other requirements of patentability." *Id.* Moreover, "[i]ntrospection and speculation into the examiner's understanding of the prior art or the completeness or correctness of the examination process is not part of the objective review of patentability." *Id.* In a nutshell, "[m]isleading statements by patent applicants, if intentionally made and material to patentability, can produce unenforceability, ***not invalidity***." *Id.* (emphasis added); *see also Magnivision, Inc. v. The Bonneau Co.*, 115 F.3d 956, 961 (Fed. Cir. 1997) (holding "prosecution irregularities" irrelevant to patent validity).

Medtronic asks the Court to ignore the legal principals set forth in *Norian* without any legal basis. While Medtronic relies upon *Surface Tech., Inc. v. U.S. ITC*, 801 F.2d 1336 (Fed.

Cir. 1986), that case does not, in any way, conflict with the principles set forth in *Norian*. In *Surface Tech.*, a trial witness had previously submitted an affidavit to the PTO that contradicted his sworn testimony at trial. 801 F.2d at 1340. Based on this fact, the Federal Circuit held that the "strength and effectiveness of the affidavits were jeopardized by the subsequent testimony of the affiants." *Id.* In other words, the Federal Circuit held that the ITC could reasonably have found that the affidavit evidence bearing on validity and the affiants' later testimony were both unreliable since they were inconsistent with one another. Contrary to Medtronic's allegation, however, *Surface Tech.* does not stand for the proposition that allegedly inaccurate statements to the PTO by a patentee have relevance to validity. (D.I. 653 at 23.)

Furthermore, Medtronic's allegation that ACS mischaracterized the Palmaz '417 patent during prosecution of the '154 patent is incorrect on the merits. Though ACS argued to the PTO that the Lau claims were patentable over this prior art patent because it failed to disclose (1) a stent with projecting edges and/or (2) a stent that does not shorten appreciably upon expansion, those statements are absolutely true. As Dr. Segal explained at trial, Palmaz '417 expressly discloses, "it is preferable that the ***outer surface*** 74 of graft, or prosthesis, 70, which would be ***in contact with the body passageway*** 80 FIG. 4, ***should be relatively smooth***." (Ex. 2, col. 8:18-20 (emphasis added); D.I. 637 at 1549.) In view of this disclosure, Palmaz '417 describes a stent that does not have projecting edges. Moreover, Dr. Segal also testified that, based on the figures in Palmaz '417, the Palmaz '417 stent appears to shorten "by about 20 percent or so" (*id.* at 1550) and that shortening greater than 10 percent is substantial (D.I. 633 at 495-96).

Although Medtronic contends that ACS's statements are misleading, Medtronic's only alleged evidence on this point relates to a commercial embodiment of the Palmaz Spiral stent sold only in Europe years after the Lau application was filed, not the Palmaz '417 patent itself.

(*See* D.I. 653 at 21-22.) Of course, such "evidence" is questionable, since Professor Saigal had never even seen a Palmaz Spiral stent[4] (D.I. 636 at 1407-08.) But even were the case otherwise, evidence of a later-developed commercial embodiment would not have established that ACS's statements regarding the disclosure of the patent itself were inaccurate. The Court's exclusion of this evidence therefore could not have affected any of Medtronic's substantial rights. *McQueeney*, 779 F.2d at 924.

E. The Court Correctly Granted JMOL on the Issue of Anticipation Based on the Palmaz '417 Patent Because Medtronic Failed to Introduce Evidence From Which a Reasonable Jury Could Find Anticipation

After the close of evidence, the Court granted ACS's motion for JMOL on anticipation, ruling that Medtronic failed to present evidence from which a reasonable jury could make a finding of anticipation:

> With respect to anticipation, try as we might, we could not cobble together a true anticipation analysis from the evidence that was proffered to us. There is no way a jury could—[Professor Saigal's] analysis wasn't couched in terms of anticipation. It was truly couched in terms of obviousness. Again, I determined there was insufficient evidence to take that issue to the jury.

(D.I. 638 at 1739-40.) Explaining that its decision was not based simply on the fact that Professor Saigal failed to say the "magic word" anticipation, the Court held, after a careful review of the record, "[w]e couldn't find the evidence."[5] (*Id.* at 1745.) Although Medtronic now

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[4] In contrast, Dr. Segal has expanded Palmaz Spiral stents, and found that they shorten approximately twenty percent, consistent with the patent disclosure. (D.I. 637 at 1551.)

[5] Medtronic's reliance on *Eolas Techs. Inc. v. Microsoft Corp.*, 399 F.3d 1325 (Fed. Cir. 2005) is inapposite. (D.I. 653 at 25.) While the *Eolas* court held that testimony related to anticipation could also support an argument for obviousness (*id.* at 1335), the Court's JMOL on anticipation in this case was not based on Medtronic's failure to use the "magic word" anticipation. (D.I. 638 at 1745.) Rather, the Court granted JMOL of no anticipation because Medtronic failed to establish that a single prior-art reference disclosed all of the features of the Lau claims. (*Id.*)

contends that Professor Saigal "established that the spiral-connector stent of the '417 patent disclosed each element of each asserted claim of the '154 and '167 patents" (D.I. 653 at 24), that simply is not true.

1. Medtronic Presented No Evidence That Palmaz '417 Discloses an "Undulating Pattern"

Professor Saigal never testified that the Palmaz '417 patent discloses an "undulating pattern," as required by each of the asserted claims of the '154 and '167 patents. The Court interpreted the term "undulating" to mean "a wavelike pattern." (DI 615 at 1.) When asked at trial what prior-art references disclose a "wavelike pattern," Professor Saigal identified the Boneau patent, the Wolff patent, and the Furui article, but never mentioned the Palmaz '417 patent:

> Q. All right. Now, sir, assuming that's the construction of the Court, do you have—did you look at the prior art to see if there were wave-like patterns?
>
> A. I did.
>
> Q. And what did you find?
>
> A. I found that there were stents in the prior art that did have the serpentine pattern as defined by ACS.
>
> Q. All right. And if we could go to the next slide, Slide 25, what does that show?
>
> A. That shows the Bonneau, the Wolff and the Furui stents, and each of them did have a serpentine pattern.

(D.I. 636 at 1300-01.)

Professor Saigal's failure to identify the Palmaz '417 patent as disclosing a "wavelike" pattern was no mistake. Immediately preceding his discussion of "wavelike," Professor Saigal testified that the Palmaz '417 patent, as well as the Wolff patent and the Furui article, each discloses U-, Y-, and W-shaped members. By deliberately omitting the Palmaz '417 patent from

the subsequent list of "wavelike" references—illustrated on a special demonstrative slide—Medtronic essentially admitted that the Palmaz '417 patent does not disclose a "wavelike" pattern, as required by the asserted claims of the '154 and '167 patents. Accordingly, Medtronic failed to prove that the Palmaz '417 patent anticipates these Lau claims.

2. Medtronic Provided No Evidence From Which a Reasonable Jury Could Conclude That Palmaz '417 Discloses "Cylindrical Elements"

Professor Saigal also failed to provide testimony from which a reasonable jury could find that the Palmaz '417 patent discloses "cylindrical elements," as recited in the claims of the '154 and '167 patents. The Court construed "cylindrical elements" to require, *inter alia*, cylindrical rings that "are *not* in and of themselves, stents." (D.I. 542 at 3 (emphasis added).) While Professor Saigal summarily concluded that Palmaz '417 discloses "cylindrical elements," he did not (and could not) opine that this reference discloses a stent made of structures that could not function independently as stents, as required by the Court's claim construction. In fact, the Palmaz '417 patent itself expressly discloses a device formed of multiple, functional stents (i.e., prostheses or grafts):

> As seen in FIG. 7, graft or prosthesis 70' generally includes a plurality of prostheses, or grafts 70 as described previously in connection with FIGS. 1A, 1B, and 2.

(Ex. 2, col. 11:48-51.) Accordingly, Medtronic also failed to establish that Palmaz '417 discloses "cylindrical elements" under the Court's interpretation of that term.[6] *See Motorola,*

[6] Medtronic cites to the following testimony by Professor Saigal: "Q. Now, in looking, in all the study and all the research that you did, sir, did you ever see anyone use one of those elements as a stand-alone stent? A. No, I did not." (D.I. 636 at 1329.) This testimony, however, is inconsistent with the Palmaz '417 patent (*see* Figs. 1A and 1B) and, even if it were accepted as true, fails to establish that each of the connected stents in Palmaz '417 would not be capable of functioning as a stent in and of itself. Indeed, based on his lack of experience and understanding of interventional cardiology, Professor Saigal is not qualified to render an opinion as to whether a particular structure would be capable of functioning as a stent. (*Id.* at 1382-83.)

Inc. v. Interdigital Tech. Corp., 121 F.3d 1461, 1473 (Fed. Cir. 1997) ("An expert's conclusory testimony, unsupported by the documentary evidence, cannot supplant the requirement of anticipatory disclosure in the prior art reference itself.").

3. Medtronic Provided No Evidence From Which a Reasonable Jury Could Conclude That Palmaz '417 Discloses a "Longitudinally Flexible Stent"

Professor Saigal also failed to provide testimony from which a reasonable jury could find that the Palmaz '417 patent discloses a "longitudinally flexible stent," as recited in the claims of the '154 and '167 patents. The Court interpreted this term to require "a stent that is flexible along its longitudinal axis (i.e. length) to facilitate delivery through tortuous body lumens." (D.I. 542 at 2.) Although Professor Saigal summarily concluded that Palmaz '417 describes a longitudinally flexible stent, he did not (and could not) provide testimony that the Palmaz '417 stent (1) is flexible along its length or (2) facilitates delivery through tortuous body lumens. (D.I. 636 at 1283.) Indeed, when asked about tortuous body lumens, Professor Saigal testified that he would not be qualified to render any opinions regarding them. (*Id.* at 1410 ("Q. And you didn't know whether doctors characterize arteries as tortuous or not in the first place? You didn't know that? A. Okay.").)

Moreover, each of the interventional cardiologists at trial, including Medtronic's witness, Dr. Pearle, agreed that a stent formed of connected Palmaz stents is a "relatively inflexible structure." (D.I. 634 at 744.) Indeed, on this point, the Court recognized that it was beyond dispute that connected Palmaz stents are not longitudinally flexible:

> I think everyone has said that the stent was relatively inflexible, which is why we went to a second generation. So we're spending an awful lot of time and controversy over an issue that I thought the parties were in agreement with.

(*Id.* at 736.) Professor Saigal's conclusory (and unskilled) testimony that Palmaz '417 discloses a "longitudinally flexible" stent does not constitute evidence from which a reasonable jury could conclude that Palmaz '417 in fact discloses this feature of the claimed invention. *Motorola*, 121 F.3d at 1473.

As explained above, Medtronic failed to present evidence that the Palmaz '417 patent discloses multiple features recited in the claims of '154 and '167 patents. Accordingly, the Court properly granted JMOL on Medtronic's anticipation defense and should deny Medtronic motion for a new trial on this ground.

F. The Court Correctly Refused to Apply the Law-of-the-Case Doctrine in the Lau Case Based on a Ruling in the Boneau Case

Medtronic contends that the Court erred by refusing to apply the law-of-the-case doctrine in the Lau case based on its prosecution-history-estoppel ruling in the Boneau case. Specifically, in its order granting summary judgment of non-infringement of the Boneau claims, the Court addressed whether prosecution history estoppel should preclude Medtronic from asserting infringement under the doctrine of equivalents. (D.I. 545 at 12-16.) To answer that question, the Court had to determine (1) whether prosecution history estoppel applied (i.e., whether there was a deliberate surrender of subject matter), and (2) the scope of the estoppel. (*Id.* at 13.) Based on the prosecution history of the Boneau patents, the Court concluded that Boneau had invited prosecution history estoppel by deliberately disclaiming any additional "elements" that would prevent the creation of "peaks" at the very top and bottom of the stent:

> During the prosecution of the '331 patent, Mr. Boneau argued that his stent was different from the Palmaz ['337] stent because his stent only had upper and lower peaks. These arguments were in response to the examiner's assertion that, due to the use of "comprising," the additional "Palmaz elements" could be added to the Boneau stent as claimed; therefore, Boneau's application encompassed prior art. Mr. Boneau asserted that these additional "Palmaz elements" could not be added because then there would

> no longer be any "peaks," as required by his claims. Therefore, it is clear that Mr. Boneau disclaimed the "Palmaz elements."

(*Id.* at 14-15.)

The Court then turned to the second step of the analysis, i.e., "determin[ing] the scope of the estoppel." As the Court noted, that step requires an examination "into the reason for, and nature of, the surrendered subject matter." (*Id.* at 14, citing *Southwall Tech., Inc. v. Cardinal IG Co.*, 54 F 3d 1570, 1580 (Fed. Cir. 1995) and *Augustine Med., Inc. v. Gaymar Indus., Inc.*, 181 F.3d 1291, 1299 (Fed. Cir. 1999).) Based on the Boneau prosecution history, the Court concluded that the examiner's rejection was based on the perceived presence of a "circular band" at one end of the Palmaz structure, "connected to two straight segments that attach adjacent circular bands." (D.I. 545 at 15.) The Court ruled that, in responding to that rejection, Boneau "explicitly surrender[ed] any 'Palmaz elements' that prevented the creation of 'peaks,' defined as either the very top or bottom." (*Id.*)

Although disagreeing with the Court's characterization of Palmaz '337 in the context of the Boneau prosecution history, Medtronic argues that this same characterization should have bound ACS for purposes of assessing the validity of the Lau patents in the Lau case. (D.I. 653 at 26 n.6, 31.) Overlooking the fact that the Boneau and Lau actions are separate cases, Medtronic argues that the Court should have applied the law-of-the-case doctrine to preclude ACS from arguing that Palmaz '337 discloses anything *other* than "circular bands" connected by "straight segments." Based on this improper attempt to invoke the law-of-the-case doctrine, Medtronic had apparently hoped to use the Court's prosecution-history-estoppel ruling in the Boneau case to argue that the Lau claims were invalid. (D.I. 653 at 31.)

Contrary to Medtronic's allegations, the Court correctly determined that its ruling in the Boneau case did not invoke the law-of-the-case doctrine in the Lau case. "Under the law of the

case doctrine, once an issue has been decided, parties may not relitigate that issue in the same case." *Waldorf v. Shuta*, 142 F.3d 601, 616 n.4 (3d Cir. 1998) (emphasis added). Here, however, the Court characterized the Palmaz '337 patent only in the context of assessing prosecution history estoppel created by Mr. Boneau during prosecution of the Boneau patents in the Boneau case. As the Court correctly held, the Boneau and Lau cases are separate cases involving different issues. (D.I. 580 at 4 ("I don't consider the Boneau case and the Lau case the same case. I would have tried them by separate juries. The conclusions we came to as to claim construction and infringement follow different paths by necessity, because they stem from different patents, different inventors, et cetera.".) Accordingly, the law-of-the-case doctrine does not apply. *Waldorf*, 142 F.3d at 616 n.4.

Moreover, neither the Lau inventors nor ACS were party to the prosecution of the Boneau patents. As such, nothing said by the examiner or Mr. Boneau during that prosecution could be possibly attributed to (or deemed an estoppel upon) ACS. While the Boneau examiner rejected the Boneau claims based on the perceived presence of a zig-zag ring within the lattice structure of the Palmaz stent (which the Court described as a "circular band"), the Boneau examiner's rejection is of course irrelevant to the Lau patents. Indeed, during prosecution of the Lau patents, ACS specifically *distinguished* the Palmaz structure as disclosing only connected stents or grafts, not "cylindrical elements" as recited in the Lau claims. (D.I. 438 at 1539-40.)

Furthermore, Medtronic had never raised an argument that the Lau claims were invalid based on the presence of "circular bands" and connectors in the Palmaz '337 patent in its pleadings, interrogatory responses, pretrial order, or expert reports submitted during discovery. By failing to raise this argument in a timely manner, Medtronic had waived it and, thus, would not have been permitted to raise it at trial anyway. *Thorn EMI N. Am., Inc. v. Intel Corp.*, 936 F.

Supp. 1186, 1191 (D. Del. 1996) (holding that the "court will prevent a party from raising a claim or defense at trial that was not adequately described in a response to a contention interrogatory or in the Joint Pre-Trial Order"); *CPC Int'l, Inc. v. Archer Daniels Midland Co.*, 831 F. Supp. 1091, 1102-03 (D. Del. 1993) (finding waiver of right to assert defense to infringement claims "both by failing to identify them in response to [plaintiff's] interrogatory and by failing to include them in the draft pretrial order").

For these reasons, the Court correctly decided that its Boneau-case rulings did not create binding law of the case in the Lau case. Accordingly, the Court should deny Medtronic's motion for a new trial on this ground.

G. The Court Properly Exercised Its Discretion to Interpret the Claims After the Close of the Evidence

Medtronic accuses the Court of committing error by issuing its final decision on claim construction after the close of evidence. (D.I. 653 at 31-33.) Specifically, Medtronic alleges that, by delaying its final claim construction decision, the Court improperly "telegraphed to the jury that the key elements of Medtronic's infringement defense were either incorrect or irrelevant." (*Id.* at 33.) Not surprisingly, Medtronic cites no legal authority in support of this allegation.

While Medtronic may have preferred an earlier claim construction, the Court had every right to wait until the close of evidence to interpret the claims. In *Exxon Chemical Patents, Inc. v. Lubrizol Corp.*, 64 F.3d 1553 (Fed. Cir. 1995), for example, the district court did precisely the same thing. Commenting that the district court waited until the close of evidence to determine claim construction, the Federal Circuit explained:

> ***No matter when or how a judge performs the Markman task***, on appeal we review the issue of claim interpretation independently without deference to the trial judge.

Id. at 1556 (emphasis added); *see also Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1580 (Fed. Cir. 1996) (noting the "district court delayed construing the disputed language until the close of testimony, at which time it ruled in favor of Conceptronic . . . ."). Addressing this very same issue, moreover, the District of Delaware has rejected a new trial request based on allegations that issuing a claim construction after the close of evidence caused undue prejudice:

> In addition to the complexity and fluidity of this action, the Court also determined that it could better understand the complex technology of the patents-in-suit if it heard the background testimony provided by both parties' expert witnesses. In the Court's view, the parties' expert testimony would give the Court the best grasp of the technology at issue, which would in turn, allow the Court to have a more complete understanding of the claims, the specifications and the prosecution histories. The Court sought the most thorough and complete understanding of the technology and the patents in order to provide the parties and the jury with the most accurate claim construction that the Court was capable of rendering. In this case, the Court was well aware of the parties' requests for claim construction at earlier stages of the case, and the Court was not oblivious to the fact that a later ruling increased the difficulty in trial preparation for the parties. However, the Court's ultimate concern was to provide the jury with a claim construction the Court had confidence in, so that the jury could perform its duty of deciding the infringement issues.

Lucent Tech., Inc. v. Newbridge Networks Corp., 168 F. Supp.2d 181, 253 (D. Del. 2001); *see also The Johns Hopkins Univ. v. Baxter Healthcare Corp.*, 894 F. Supp. 819, 826 (D. Del. 1995) ("Not having had the opportunity to review the claim construction issue prior to trial, the court endeavored to decide this issue after having heard the necessary evidence and argument.").

On the timing of claim construction, the Federal Circuit has held, "Markman does not obligate the trial judge to conclusively interpret claims at an early stage in a case." *Sofamor Danek Group, Inc. v. Depuy-Motech, Inc.*, 74 F.3d 1216, 1221 (Fed. Cir. 1996). Rather, the "trial court may exercise its discretion to interpret the claims at a time when the parties have presented a full picture of the claimed invention and prior art." *Sofamor Danek*, 74 F.3d at 1221.

Furthermore, the Federal Circuit has also held that the court may engage in a "rolling" claim construction in which it revisits and alters its construction throughout the case:

> District courts may engage in a rolling claim construction, in which the court revisits and alters its interpretation of the claim terms as its understanding of the technology evolves. This is particularly true where issues involved are complex, either due to the nature of the technology or because the meaning of the claims is unclear from the intrinsic evidence.

Jack Guttman, Inc. v. Kopykake Enter., Inc., 302 F.3d 1352, 1361 (Fed. Cir. 2002) (internal citations omitted); *see also Ballard Med. Prods. v. Allegiance Healthcare Corp.*, 268 F.3d 1352, 1358 (Fed. Cir. 2001) ("District courts have wide latitude in how they conduct the proceedings before them, and there is nothing unique about claim construction that requires the court to proceed according to any particular protocol.")

In accordance with these principles, the Court properly exercised its discretion to interpret the claims only after the parties had presented all of their evidence relating to the claimed invention:

> Basically, as far as I'm concerned, you both can present whatever you believe to be the proper claim construction and ***I will decide during the jury instruction portion which claim construction is the one most consistent with the evidence and with the patent***

(D.I. 631 at 89 (emphasis added).) Furthermore, to minimize any prejudice to the parties, the Court instructed the jury on this point:

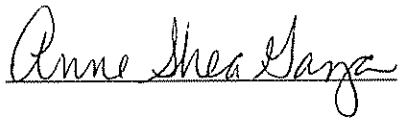
> The question of what a claim term means, called a claim construction, is an issue for the Court to decide. You should know that ***I have not yet construed the claim term cylindrical element. I will provide you with a construction of that claim term for your determination of whether the patents are infringed and/or are invalid at the close of evidence, before you are asked to deliberate and reach a verdict in this case***. Until then, you should continue listening to the evidence that the parties present on the meaning of the claim term cylindrical element and how that may impact your verdict on the issues of infringement and invalidity.

(D.I. 634 at 680-81 (emphasis added).)

Based on Federal Circuit precedent, the Court's decision to issue its final claim construction ruling after it had an opportunity to consider all of the relevant evidence was well within its discretion. *Sofamor Danek*, 74 F.3d at 1221; *Jack Guttman*, 302 F.3d at 1361; *Lucent*, 168 F. Supp.2d at 253. Therefore, the Court should deny Medtronic's motion for a new trial on this basis.

V. CONCLUSION

For the foregoing reasons, ACS requests that the Court deny Medtronic's motion for a new trial.



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Dated: June 17, 2005

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ADVANCED CARDIOVASCULAR SYSTEMS, INC. and GUIDANT SALES CORPORATION, Plaintiffs, v. MEDTRONIC VASCULAR, INC. and MEDTRONIC USA, INC., Defendants.	Civil Action No. 98-80 (SLR) (Consolidated with C.A. No. 98-314 (SLR) and C.A. No. 98-316 (SLR))

ORDER

The Court, having considered Medtronic's Motion for New Trial Pursuant to Fed. R. Civ. P. 59(a), and the parties' positions related thereto,

IT IS HEREBY ORDERED this ____ day of _____, 2005 that the Motion is DENIED.

_____
UNITED STATES DISTRICT COURT JUDGE